IDPH IOWA Department of PUBLIC HEALTH
Protecting and Improving the Health of Iowans
Kim Reynolds, Governor | Adam Gregg, Lt. Governor | Kelly Garcia, Interim Director

COVID-19 Therapeutics Information Brief

May 18, 2022

Changes to the document from the previous version are highlighted in yellow.

The next Therapeutics Information Brief will be June 1, 2022.

IMPORTANT/NEW COVID-19 Therapeutics Information

- Clinical Resources for Paxlovid
- Renal Packaging for Paxlovid 150mg; 100mg Dose Pack for Patients with low eGFR
- Bamlanivimab Self-Life Extension
- Test to Treat Program
- Guidelines for Product Return
- Sotrovimab is NO Longer Authorized to Treat COVID-19 Vaccine in any U.S. Region
- Return of bam/ete and REGEN-COV NOT Recommended
- Allocation Cadence Changes for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals
- Therapeutic Reporting Reminder
- Reporting Wastage Guidance
- Allocations Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Oral Antivirals
- COVID-19 Therapeutics Information Resources

Clinical Resources for Paxlovid - NEW!

Paxlovid is now widely available. Although COVID-19 hospitalizations have decreased, some high-risk patients are becoming ill enough to require hospital admission. Early treatment with Paxlovid and other available authorized or approved therapeutics could make a difference. FDA has released a new Paxlovid Patient Eligibility Screening Checklist for Prescribers. This checklist is intended as an aid to support clinical decision making for prescribers. However, use of this checklist is not required to prescribe Paxlovid under the EUA.

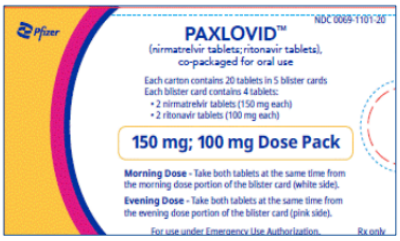
- Paxlovid Patient Eligibility Screening Checklist Tool for Prescribers
- University of Liverpool COVID-19 Drug Interactions
- Pfizer Drug Interaction Checker
- NIH COVID-19 Treatment Guidelines -Ritonavir-Boosted Nirmatrelvir(Paxlovid)
- CDC/IDSA COVID-19 Clinician Call: All About Paxlovid; Plus Variants Update

Renal Packaging for Paxlovid 150mg; 100mg Dose Pack for Patients with low eGFR

FDA updated the Paxlovid EUA to authorize an additional dose pack presentation of Paxlovid with appropriate dosing for patients within the scope of this authorization with **moderate** renal impairment.

- Each 150 mg; 100 mg Dose Pack includes 5 daily blister cards
- Each blister card contains a morning and evening dose
- Each dose consisting of 150mg nirmatrelvir (one oval, pink 150 mg tablet) and 100mg ritonavir (one white or white to off-white film-coated 100mg tablet uniquely identified by the color, shape and debossing)

The HCP and Pharmacist Instructions are available at: https://www.covid19oralrx-hcp.com/resources



Standard Dose	Renal Dose
300 mg nirmatrelvir;100 mg ritonavir: Each carton contains 30 tablets divided in 5 daily dose blister cards. Each blister card contains 4 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.	150 mg nirmatrelvir;100 mg ritonavir: Each carton contains 20 tablets divided in 5 daily dose blister cards. Each blister card contains 2 nirmatrelvir tablets (150 mg each) and 2 ritonavir tablets (100 mg each). Nirmatrelvir tablets and ritonavir tablets are supplied in separate blister cavities within the same child-resistant blister card.

If the renal packaging of Paxlovid is not available, healthcare providers may use the standard dose pack of Paxlovid and adjust the dosing per the Dear HCP Letter guidance issued by the FDA for patients with renal impairment.

Bamlanivimab Self-Life Extension

On May 4, 2022, the FDA authorized the shelf-life extension for specific lots of the refrigerated Eli Lilly monoclonal antibody, bamlanivimab, **from 18 months to 24 months.** Due to the high frequency of the Omicron variant across the country, bamlanivimab and etesevimab are not currently authorized in any U.S. region. These drugs may not be administered for treatment or post-exposure prophylaxis of COVID-19 under the EUA until further notice by the FDA.

It is the recommendation of the U.S. Government that the product be retained in the event that future SARS-CoV-2 variants, which may be susceptible to bamlanivimab and etesevimab, emerge and become prevalent in the United States. Retained product must be appropriately held in accordance with storage conditions detailed in the authorized Fact Sheet for Health Care Providers and the Letter of Authorization for Emergency Use Authorization (EUA) 094.

Evaluation of future extension of shelf-life for etesevimab is ongoing and an update regarding shelf-life extension for etesevimab is planned for November 2022.

Test to Treat Program

The Biden-Harris Administration launched a new nationwide Test to Treat initiative in March to give individuals an important way to quickly access free lifesaving treatment for COVID-19. The recently launched Test to Treat program supports this priority effort by creating an additional pathway for fast access to lifesaving COVID-19 treatments.

The federally managed Test to Treat program will focus on Federal Retail Pharmacy Therapeutic Program (FRPTP) partners and associated sites; all other sites will be managed by the state and receive state distributions from the weekly state allocation.

The following considerations should be taken by healthcare providers interested in participating in the Test to Treat Program:

- Provide/offer comprehensive end-to-end test and treat services to support a seamless patient experience:
    - COVID-19 testing on-site (or evaluation of at-home testing)
    - Linkage to a clinical evaluation by licensed healthcare provider after positive result to provide prescription when appropriate
- Co-located or affiliated pharmacy able to readily dispense medication to eligible patients
    - Provide services to all individuals, regardless of insurance status
    - Accept new patients for priority same-day or next-day visit for COVID-19 services

Healthcare providers interested in participating in the Test to Treat Program should contact the COVID-19 Therapeutics Call Center at: C19Therapeutics@idph.iowa.gov or (515) 281-7317.

Guidelines for Product Return

All therapeutic products are property of the United States Government and must be used in accordance with EUA guidance. Sites of care cannot donate products to entities outside the U.S. or for use outside the U.S. Any returned product will be destroyed, as product integrity cannot be verified. Non-expired products should not be destroyed. Any returned product needs to be quantified by the United States Government.

- Email the IDPH COVID-19 Therapeutics Call Center on the intent to return products
- Long-term utility of authorized mAb products is expected
- After consultation with the IDPH COVID-19 Therapeutics Call Center, if undamaged product needs to be returned, follow the below instructions:
    - For bam and bam/ete, see The Lilly Return Goods Procedure, detailed guidance can be found at: https://www.lillytrade.com/
    - For REGEN-COV, call 844-734-6643
    - Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per the facility's standard operating procedures

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Sotrovimab is NO Longer Authorized to Treat COVID-19 in any U.S. Region

As of 04/05/2022, the FDA has updated the Sotrovimab Emergency Use Authorization stating **Sotrovimab is no longer authorized to treat COVID-19 in any U.S. region due to increases in the proportion of COVID-19 cases cases caused by the Omicron BA.2 sub-variant.** FDA will continue to monitor BA.2 in all U.S. regions and will provide follow-up communication when appropriate.

The Centers for Disease Control and Prevention (CDC) Nowcast data from April 5, 2022, estimates that the proportion of COVID-19 cases caused by the Omicron BA.2 variant is above 50% in all Health and Human Services (HHS) U.S. regions. Data included in the health care provider fact sheet show the authorized dose of sotrovimab is unlikely to be effective against the BA.2 sub-variant. Due to these data, sotrovimab is not authorized in any U.S. state or territory at this time.

Health care providers should use other approved or authorized products as they choose appropriate treatment options for patients. Currently authorized alternative treatments are available for distribution. These include, Paxlovid (an oral antiviral treatment) and molnupiravir (an alternative oral antiviral for patients for which Paxlovid is not appropriate or accessible). Additionally, bebtelovimab is an alternative monoclonal antibody therapy that is currently authorized and available for distribution. Based on similar in vitro assay data currently available, these products are likely to retain activity against the BA.2 variant.

Healthcare providers should review the Antiviral Resistance information in Section 15 of the authorized Fact Sheets for each monoclonal antibody and oral antiviral therapy available under an EUA for details regarding specific variants and resistance. Healthcare providers should also refer to the CDC website (https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/variant-proportions.html) and information from state and local health authorities regarding reports of viral variants of importance in their region to guide treatment decisions.

- COVID-19 Therapeutics Clinical Decision Aids

Return of bam/ete and REGEN-COV NOT Recommended

Product return of bam/ete and REGEN-COV is ***NOT*** recommended as any returned product has to be destroyed. The COVID-19 environment remains dynamic and these products may be effective against future variants. Current supplies of bamlanivimab plus etesevimab and Regeneron's casirivimab plus imdevimab (REGEN-COV) should be retained by healthcare providers for potential use for other COVID variants. If healthcare providers have storage concerns or challenges, consider transferring products to another location/site in the region or health system.

If product must be returned, please follow the guidance below:

- Email the IDPH COVID-19 Therapeutics Call Center on the intent to return products
- For bam/ete, see The Lilly Return Goods Procedure; detailed guidance can be found at: https://www.trade.lilly.com/assets/pdf/lilly-product-return-procedure.pdf
- For REGEN-COV, call 844-734-6643
- Note: Reconstituted (diluted) product SHOULD NOT be returned and should be treated as waste per the facility's SOP

Allocations Cadence Changes for Monoclonal Antibodies, PReP Treatment and Antivirals

Antivirals will shift to a weekly allocation cycle. This will align with the weekly allocation cadence for monoclonal antibodies (Bebtelovimab and sotrovimab) and the pre-exposure prophylaxis treatment (Evusheld). The ordering cadence will be as follows:

- Allocation Survey Sent - Monday
- Allocation Survey Due Back to IDPH - Tuesday at 4:00pm
- Allocation Ordered in Federal System - Thursday
- Allocation Amount Notification from IDPH to healthcare providers - Thursday

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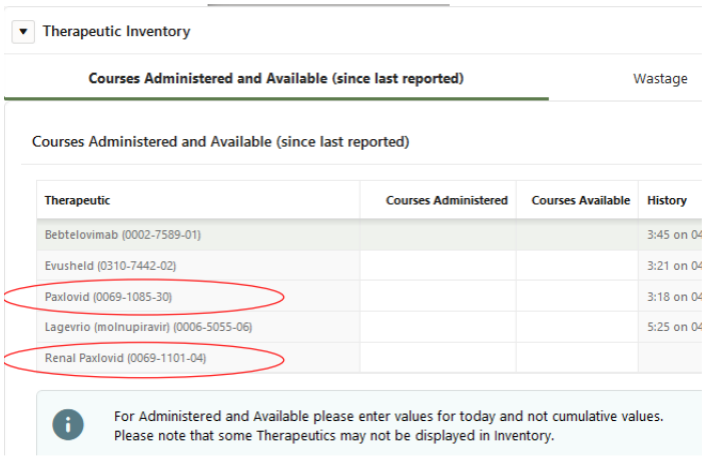
Therapeutic Reporting Reminder

Sites receiving monoclonal antibodies, pre-exposure prophylaxis treatment, or oral antivirals MUST comply with federal reporting requirements.

Failure to comply with reporting requirements may result in the loss of COVID-19 therapeutic providers status and removal of COVID-19 therapeutic products. **Reporting requirements are as follows:**

- Monoclonal antibodies (REGEN-COV, bamlanivimab/etesevimab, sotrovimab): Report on-hand and usage data **every Wednesday** in NHSN (for long-term care facilities) or Teletracking (for all other sites including hospitals).
- Pre-exposure prophylaxis treatment and oral antivirals (Evusheld, Paxlovid, Molnupiravir and Bebtelovimab): Report on-hand and usage data **daily** in HPoP.
- Reporting should include product doses utilized since the last report date
- Reporting **IS NOT** a cumulative total of all doses utilized to date
- Please contact C19therapeutics@idph.iowa.gov for assistance with HPoP

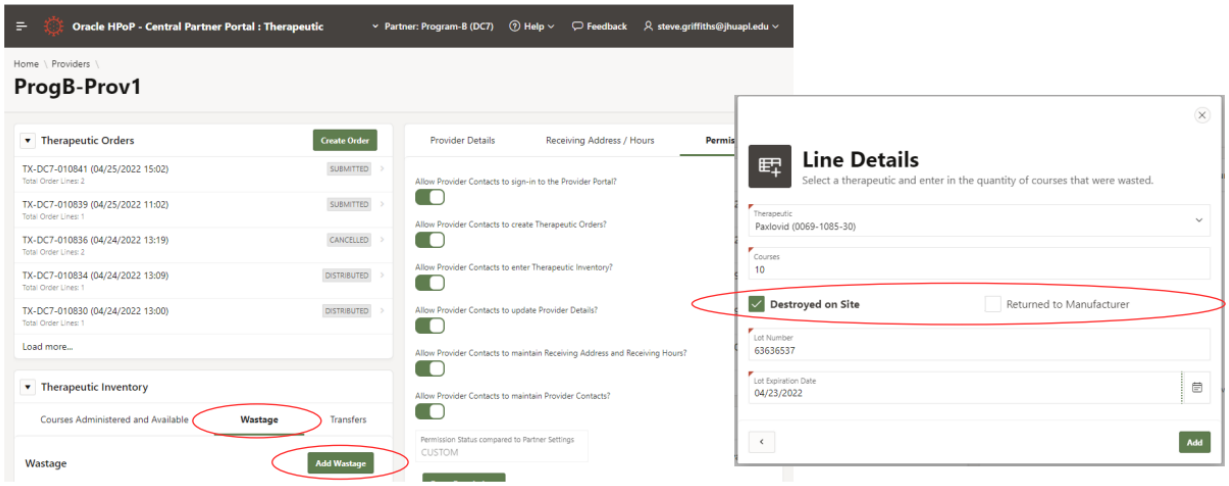
Healthcare providers should ensure reporting of the correct Paxlovid or Renal Paxlovid product. Paxlovid (renal) was renamed as Renal Paxlovid and the display order was changed to separate the Paxlovid products.



Reporting Wastage Guidance

In the Provider or Partner Portal, a new tab has been added in the Therapy Inventory section – Wastage. Wastage will be reported for all therapeutic products except Sotrovimab. Wastage now includes returned to manufacturer/destroyed onsite options. The following steps outline the reporting of wastage of COVID-19 Therapeutics in HPoP:

- Choose wastage, then select the green “Add Wastage” button. A blank report appears.
- Enter the wastage date, the reason for the wastage (expired, damaged, temp excursion, or other).
    - A provider contact may be chosen, or is predetermined.
    - A description can be added.
- Upon selecting Add Therapeutic, a second window will open allowing details for each line in the wastage report to be entered. Select the therapeutic from drop down, enter the number of courses, a lot number and the lot expiration date.



Allocations Threshold Remaining for Monoclonal Antibodies, Pre-Exposure Prophylaxis Treatment and Antivirals

Iowa Statewide Allocations Threshold Remaining for the week Monday, May 16, 2022 - Sunday, May 22, 2022				
mAbs	Oral AVs			PrEP
Bebtelovimab	Mulnupiravir (Lagevrio)	Paxlovid	Renal Paxlovid	EVUSHELD
185 courses	**384 courses**	**880 courses**	**80 courses**	**15290doses** (monthly allocation)

- The minimum order quantity for Molupiravir is 24 courses.
- **Allocations will not include sotrovimab, bamlanivimab plus etesevimab and casirivimab plus imdevimab (REGEN-COV).**
- **IDPH encourages entities who do receive allocations of therapeutic products to notify and work with prescribers and LPHAs on the availability of therapeutic products in the community.**
- The Department of Health and Human Services has released a COVID-19 Therapeutics locator.

COVID-19 Therapeutics Information Resources

- **COVID-19 Therapeutics Call Center -** To reach the IDPH COVID-19 Therapeutics Call Center, call **515-281-7317**.
- **COVID-19 Therapeutics Email -** Therapeutic questions from healthcare providers can be emailed to: C19Therapeutics@idph.iowa.gov
    - NOTE: **The COVID-19 Therapeutics Call Center and Email are intended for healthcare providers only.**
- **COVID-19 Therapeutics Table-** IDPH has developed a table of therapeutic products available for the treatment or prevention of COVID-19.
- Outpatient Therapeutics Decision Aid
- Side-by-Side Overview Outpatient Therapeutics
- Product Expiration Date Extensions
- NIH COVID-19 Treatment Guidelines, last updated: April 8, 2022